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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/541,033 03/31/00 MILLER

R 35828-0079

HM22/0905

EXAMINER

MR ROLAND H JOACHIM  
RIDOUT & MAYBEE  
ONE QUEEN STREET EAST  
SUITE 2400  
TORONTO ON M5C 3  
CANADA

ROARK, J

AIR MAIL

ART UNIT	PAPER NUMBER
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1644

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**DATE MAILED:**

09/05/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

<b>Office Action Summary</b>	Application No. <b>09/541,033</b>	Applicant(s) <b>Miller et al.</b>
	Examiner <b>Jessica Roark</b>	Group Art Unit <b>1644</b>

Responsive to communication(s) filed on \_\_\_\_\_.

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 1-11 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) \_\_\_\_\_ is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims 1-11 are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

## DETAILED ACTION

### *Species Election*

1. **Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

2. This application contains claims directed to the following patentably distinct species of the claimed Invention:

A) wherein the disease is:

- i) rheumatoid arthritis,
- ii) multiple sclerosis,
- iii) SLE,
- iv) scleroderma,
- v) diabetes,
- vi) inflammatory bowel disease,
- vii) psoriasis,
- viii) atherosclerosis,
- ix) graft versus host disease, or
- x) transplant rejection;

These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints.

B) wherein the stressor is:

- i) oxidative environment,
- ii) electromagnetic emission,
- iii) temperature above body temperature,
- iv) temperature below body temperature,
- v) temperature below body temperature and an oxidative environment,
- vi) temperature below body temperature and electromagnetic emission,
- vii) temperature below body temperature and electromagnetic emission and oxidative environment,
- viii) temperature above body temperature and an oxidative environment,
- ix) temperature above body temperature and electromagnetic emission,
- x) temperature above body temperature and electromagnetic emission and oxidative environment, or
- xi) oxidative environment and electromagnetic emission;

These species are distinct because they differ with respect to their properties and modes of action.

C) wherein the therapeutic treatment comprises the TNF inhibitor:

- i) p55 TNFR:Fc,
- ii) p75 TNFR:Fc,
- iii) anti-TNF monoclonal antibodies, or
- iv) (4-(3-cyclopentyloxy-4-methoxyphenyl)-2-pyrrolidone;

These species are distinct because their structures and modes of action are different.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

3. Applicant is advised that a response to this requirement must include an identification of the species that is elected *from each of groups A, B, AND C*, consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

4. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

6. A telephone call was made to Roland Joachim on 8/31/00 to request an oral election to the above species requirement, but did not result in an election being made. A written requirement was requested.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica Roark whose telephone number is (703) 605-1209. The examiner can normally be reached Monday through Friday from 8:00 am to 4:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Jessica Roark, Ph.D.  
Patent Examiner  
Technology Center 1600  
September 1, 2000

PHILLIP GAMBEL  
PHILLIP GAMBEL, PH.D  
PRIMARY EXAMINER  
TECH CENTER 1600  
9/15/00